

REMARKS

Upon entry of the amendment, claims 31, 32, 56, 58, 62-66, 73-, 75-80, and 82-108 are pending and subject to examination. Applicants' remarks are prefaced by text from the most recent Office Action in small bold type.

Rejection for Alleged Indefiniteness re: Interactions with the Transporter Polypeptide

The Examiner state on page 3:

The rejection of claims 53, 59, 64-71, 83, and 84 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record on p. 3 of the office action of paper no. 0404. Claims 53, 59, and 64-67 are now drawn to detecting an "activity-modulating interaction". This limitation is still vague and indefinite. One skilled in the art would not be able to read the claims and know whether or not they were practicing the claimed invention. It appears that Applicants are intending to claim binding assays or assays which screen for modulators of transport activity of SEQ ID NO: 2. The claims are missing steps which detail what is being measured. For example, claim 53 reads "a method to assess interaction of a test molecule with a transporter polypeptide" by "detecting interaction of the test molecule with the transporter polypeptide, wherein the interaction is a binding interaction or an activity-modulating interaction". What does the activity-modulating interaction indicate? Is the test molecule an inhibitor, an antagonist, an agonist? The claims need to be amended so that they clearly detail the methods being claimed.

Claims 53, 59, and 67-71 are cancelled without prejudice. Because claims 64-66 no longer depend from claim 53, the rejection should no longer apply to these claims. Without acceding to the merits of the rejection, claims 83 and 84 have been amended to detail what is being measured. The test molecule can be any molecule. Results of the method may indicate that the test molecule is an inhibitor, an antagonist, or an agonist. The method is not limited by the result obtained in a particular case.

Rejection for Alleged Indefiniteness re: Rate of Aging

The Examiner stated on page 3:

The rejection of claims 67, 71, and 83-103 under 35 U.S.C. 112, second paragraph, is maintained for reasons of record p. 5 of the office action of paper no. 0404. Claims 67, 71, and 83-103 have been amended so that they are drawn to methods of "detecting rate of aging", however the

specification does not define what is being measured by measuring the rate of aging. The specification teaches that increased life span is a measurable indication of aging, yet the claims potentially encompass far more than increased life span. For instance, free radical damage in a cell is a symptom of aging, yet one of skill in the art would not know whether such a method is meant to be encompassed by the claims. The rejection could be obviated by amending the claims to read "measuring the life span of the cell" so long as there is written support for the amendment in the specification.

Without conceding the point, claims 67 and 71 have been cancelled without prejudice. The Applicants respectfully traverse with respect to claims 83-103. The contention of indefiniteness for the phrase "detecting the rate of aging" is that "one skilled in the art would not know whether a method of detecting free radical damage is encompassed by the claims." As noted in MPEP § 2173.04, "breadth of a claim is not to be equated with indefiniteness." The Examiner herself correctly recognizes that symptoms of aging can be indicative of the rate of aging. Many such symptoms were well known in the art at the time of filing and are appropriate indicia for detecting the rate of aging. Given that the term "rate of aging" is well recognized and correctly understood by the Examiner, the Applicants are unclear as to why the Examiner is of the position that one skilled in the art would be uncertain of the scope of the claim. The Applicants respectfully submit that claims 83-103 are definite. If the rejection is maintained, the Applicants respectfully request that the Examiner explain why the term "rate of aging" would not be understood by one skilled in the art.

Omission of Essential Steps

The Examiner stated on pages 3-4:

Claims 31, 53, 54, 58, 61-63, 67-71, 82-94, and 103 are newly rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: having the polypeptide be expressed in a cell.

Without conceding the point, claims 31 and 58 have been amended. The claims 31 and 82-84 now indicate that the polypeptide has been expressed by a cell. A polypeptide so expressed can be evaluated, for example, in a cell or a liposome

reconstituted from the cell. Claim 58 indicates the transporter polypeptide is expressed in a host cell such that the transporter polypeptide is present at the cell surface. Claims 62-63 now depend from amended claim 58.

The Examiner stated on page 4:

Claims 31, 61-63, and 82 encompass measuring the amount of carboxylate that is transported, however the claims fail to explain the presence of the carboxylate.

Without conceding the point, claims 31 and 82 have been amended to explain the presence of a carboxylate.

Rejection for Alleged Indefiniteness re: Rate of Aging

The Examiner stated on page 4:

Claims 73 and 75-80 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 73, as amended, reads "a method to assess a cell". The method is drawn to detecting expression of mRNA which encodes SEQ ID NO: 2. Similarly, claim 75, as amended, is drawn to a method "to assess a cell," wherein "transporter activity" of the cell is detected. The methods are missing an essential method step, because the methods do not teach how the cell is being assessed. Applicants do not teach what is being measured.

Claims 73 and 75 have been amended. To the extent that the preambles of these claims did not clearly delineate "what is being measured," the preambles have been amended to indicate what is being assessed. In the method of claim 73, the cell can be assessed by any method for evaluating mRNA or protein. Such methods would indicate whether the test molecule can modulate expression of the transporter polypeptide in the cell. In the method of claim 75, as currently amended, the cell is being assessed by detecting transport of a carboxylate.

In addition, the nucleic acid encoding SEQ ID NO: 2 must have a promoter to allow for generation of mRNA. Also, the limitation of "providing a cell that contains a nucleic acid encoding a transporter" allows for both DNA and mRNA. If Applicants intend for it to be mRNA, it would be indistinguishable from the mRNA being measured in the last step of the claim. The claims are also missing steps which indicate what an increase in expression of mRNA represents.

Applicants respectfully traverse. The nucleic acid may be an mRNA, e.g., an mRNA injected into a *Xenopus* oocyte. Such nucleic acids do not require a promoter. In embodiments where such mRNA is being detected or measured, it is of little import that the mRNA might be indistinguishable from the injected mRNA. For example, the test molecule (including, e.g., an anti-sense RNA or ribozyme) might alter mRNA stability or processing and thereby modulate expression of the transporter polypeptide. Test molecules can also affect the translation of an mRNA, thereby modulating expression of the mRNA into protein. Finally, one skilled in the art would recognize that a change in expression of the mRNA would represent, *inter alia*, a change in the number of transporter polypeptides, and hence transporter activity in a cell. Applicants respectfully submit that claim 73 clearly and distinctly points out the subject matter being claimed.

In addition, claim 75 is drawn to "detecting a transporter-activity of the cell". The activity is not of the cell, but rather of the polypeptide comprising SEQ ID NO: 2. The claim should be amended to reflect that the activity is of the transporter polypeptide that comprises SEQ ID NO: 2.

The preamble of claim 75 has been amended to clarify that it is drawn to a method to assess transport activity by a transporter polypeptide.

Rejection for Lack of Enablement

The Examiner made an enablement rejection against claims 53, 59, and 64-67. Without conceding the point, these claims have been canceled without prejudice.

Objection to Claim 56

The Examiner noted

Claims 32 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims.

Claim 56 has been written in independent form.

Applicant : Robert A. Reenan et al.
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Page : 15 of 15

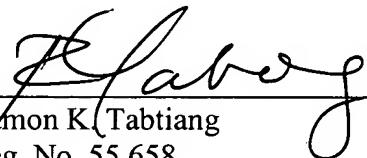
Attorney's Docket No.: 13407-012001 / 00-066

The Applicants respectfully submit that all claims are in condition for allowance, which action is expeditiously requested. The Applicants do not concede any positions of the Examiner that are not expressly addressed above. All amendments and cancellations are made without prejudice and disclaimer and may be made for reasons not explicitly stated or for reasons in addition to ones stated.

Enclosed is a Petition for Extension of Time and a check for the required fee. Please apply any other charges (including charges for excess claims) to deposit account 06-1050, referencing attorney docket number 13407-012001.

Respectfully submitted,

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